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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Chris Kornak at 240-627-3705 or *Chris.Kornak@nih.gov.* Licensing information may be obtained by communicating with the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD 20852; tel. 301-496-2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished information related to the invention.

SUPPLEMENTARY INFORMATION: Technology description follows:

Replication-Competent Adenovirus Type-4 HIV Env Vaccines and Their Use.

Description of Technology:

National Institute of Allergy and Infectious Diseases (NIAID), International AIDS Vaccine Initiative (IAVI), Emergent, and Scripps have developed two recombinant adenovirus type 4 (Ad4) vector-based vaccine candidates. These replicating Ad4 vector-based candidates have shown improved activity against tier 2 HIV-1 isolates in experimental animals. Tier 2 isolates are among the most prevalent in infected populations. The two candidates, Ad4-Env150KN and Ad4-Env145NFL, incorporate

novel design features based on Ad4-EnvC150 (1086c). Specifically, the truncation of the cytoplasmic tail of Env increases cell surface expression and has resulted in improved antigenicity from both candidates.

Additionally, the upper respiratory tract administration offers a way to bypass pre-existing Ad4 immunity in most people. Furthermore, unlike non-replicating vectors, these vaccines may evoke a durable immune response.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404, as well as for further development and evaluation under a research collaboration.

Potential Commercial Applications:

- Prophylaxis against HIV-1.

Competitive Advantages:

- Replicating vector may invoke durable immunity against HIV-1.
- Potential for prophylactic use in high-risk populations.
- Upper-respiratory (intranasal) administration will bypass pre-existing Ad4 immunity in most people.

Development Stage:

- Phase 1 Clinical Trial (NCT03878121)

Inventors: Mark Connors (NIAID), Jeff Alexander (Emergent), Lo Vang (Emergent), Richard Wyatt (Scripps and IAVI), and Javier Guenaga (IAVI).

Publications: Alexander J, Mendy J, Vang L, Avanzini JB, Garduno F, et al. (2013) Pre-Clinical Development of a Recombinant, Replication-Competent Adenovirus Serotype 4 Vector Vaccine Expressing HIV-1 Envelope 1086 Clade C. PLOS ONE 8(12): e82380. https://doi.org/10.1371/journal.pone.0082380.

Intellectual Property: HHS Reference No. E-105-2020-0-PCT-01—PCT Application No. PCT/US21/45389 filed on 10 August 2021.

Licensing Contact: To license this technology, please contact Chris Kornak at 240-627-3705 or Chris.Kornak@nih.gov, and reference E-105-2020.

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize this technology. In particular, NIAID would be very interested in a partnership with an entity that has a complementary HIV vaccine technology. For collaboration opportunities, please contact Chris Kornak at 240-627-3705 or Chris.Kornak@nih.gov.

Dated: April 25, 2022.

Surekha Vathyam,

Deputy Director,

Technology Transfer and Intellectual Property Office,

National Institute of Allergy and Infectious Diseases.

[FR Doc. 2022-09158 Filed: 4/27/2022 8:45 am; Publication Date: 4/28/2022]